DEC - 4 2000

SECTION 7

SUMMARY OF SAFETY AND EFFECTIVENESS

K003587

510(k) Summary of Safety and Effectiveness

Information supporting claims of substantial equivalence, as defined under the Federal Food, Drug and Cosmetic Act, respecting safety and effectiveness is summarized below. For the convenience of the Reviewer, this summary is formatted in accordance with the Agency's final rule "...510(k) Summaries and 510(k) Statements..." (21 CFR 807) and can be used to provide a substantial equivalence summary to anyone requesting it from the Agency.

NEW DEVICE NAME: CLEARGLIDE Precision Bipolar Device

PREDICATE DEVICE NAME: VasoView Uniport BiSector

510(k) SUMMARY

Device Description

The CLEARGLIDE Precision Bipolar Device is a sterile, bipolar electrosurgical instrument with features to dissect, coagulate, and transect (cut) tissue with an integral knife blade. The device is compatible with a 5mm trocar and utilizes bipolar energy from standard bipolar generators.

The instrument consist of three main parts as follows:

(1) The in-line handle with slide buttons to actuate the jaw for clamping and cutting with integral knife. Attached to the handle is the standard pigtail cord, (2) a shaft, that is approximately 5mm in diameter and is 42 cm in length from the handle (distal end) to the tip of the end effectors, and (3) the working end (end effectors) of the instrument. The working end is composed of a pair of jaws for clamping tissue (vessels), electrode surfaces for bipolar energy delivery to achieve coagulation of tissue, and embedded knife for vessel transection. Tissue dissection is achieved at the distal end of the instrument shaft where the closed jaws form a V-shape for separating tissue layers and exposing the knife blade to tissue.

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Device Description (continued)	The device is primary packaged in a labeled overwrap package that serves at the sterility barrier and placed in a labeled carton.
Intended Use	The CLEARGLIDE Precision Bipolar Device is indicated for endoscopic and open tissue dissection, bipolar coagulation, and transection of vessels.
Indications Statement	The CLEARGLIDE Precision Bipolar Device is indicated for endoscopic and open tissue dissection, bipolar coagulation, and transection of vessels.

Continued on next page

510(k) SUMMARY, Continued

Technological Characteristics

The technological characteristics of the new device are the same as the predicate device in that they both are electrosurgical devices that use bipolar electrical energy to provide coagulation, powered by electrosurgical generators, connected by cable, activated by a footpedal and cutting (transection) by a knife. The new device is designed with tissue dissection capabilities.

Performance Data

Preclinical laboratory evaluations were conducted to assess the performance characteristics of the new device when compared to the predicate device. Clinical data was deemed unnecessary to demonstrate equivalence of the new device to the predicate device for its intended purpose.

Conclusions

Based on the 510(k) summaries and 510(k) statements (21 CFR 807) and the information provided herein, we conclude that the new device is substantially equivalent to the Predicate Device under the Federal Food, Drug, and Cosmetic Act.

Contact

Gregory R. Jones
Director, Regulatory Affairs
ETHICON, Inc.
Rt. #22, West
Somerville, NJ 08876-0151

Date

November 3, 2000

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 1 5 2001

Ethicon
c/o Mr. Robert Mosenkis
President
CITECH, Inc.
5200 Butler Pike
Plymouth Meeting, Pennsylvania 19462

Re: K003587
Trade/Device Name: CLEARGLIDE Precision Bipolar Device
Regulation Number: 878.4400
Regulatory Class: II
Product Code: GEI
Dated: November 20, 2000
Received: November 21, 2000

Dear Mr. Mosenkis:

This letter corrects our substantially equivalent letter of December 4, 2000, regarding the address.

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval) it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General (QS) regulation (21 CFR Part 820) and that, through periodic QS inspections, FDA will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, the Food and Drug Administration (FDA) may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to continue marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594- 4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at their toll free number (800) 638-2041 or at (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATION FOR USE

510(k) Number (if known): K003587

Device Name: CLEARGLIDE Precision Bipolar Device

Indications for Use: The CLEARGLIDE Precision Bipolar Device is indicated for endoscopic and open tissue dissection, bipolar coagulation, and transection of vessels.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The Counter Use _____
(Per 21 CFR 801.109)

(Optional Format 1-2-9G)

for Mark N Milham

(Division Sign-Off)
Division of General [illegible]

510(k) Number K003587